UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/922,532	08/03/2001	Endre Markovits Schersl	06965-1001	9018

7590 05/24/2006

David I Roche
Baker & McKenzie
130 E. Randolph Drive
Chicago, IL 60601

EXAMINER	
BADIO, BARBARA P	

ART UNIT	PAPER NUMBER
1617	

DATE MAILED: 05/24/2006

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/922,532	SCHERSL ET AL.	
	Examiner	Art Unit	
	Barbara P. Badio, Ph.D.	1617	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 36-55 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) 36-55 is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

First Office Action on the Merits of a RCE

1. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

2. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

3. Claims 36-55 are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention.

The instant claims recite ranges not disclosed by the present specification. For example, claim 36 recites weight percentage of 0.01-10.0 octadecanol, 10.0-60.0 docosanol and 1.0-30.0 hexacosanol. The present specification lacks support for these ranges and, thus, does not convey to the skilled artisan in the art that applicant, at the time the application was filed, had possession of the claimed invention.

Note: It is requested that applicant points to support for each of the recited range in the present specification.

Claim Rejections - 35 USC § 112

4. The rejection of claims 36-38, 40-46, 48, 50, 52 and 54 under 35 USC 112, second paragraph is withdrawn.

Claim Rejections - 35 USC § 103

5. The rejection of claims 36-55 under 35 USC 103(a) over Sorkin, Jr. (US 5,952,393), Gamble et al. (US 6,596,776), Maurel et al. (US 6,129,924) and Milstein et al. (US 6,394,230) in combination is withdrawn.

Note the examiner's response to the instant rejection below in #7. The examiner notes that the instant rejection was withdrawn in favor of the combination of reference cited below in #6.

6. Claims 36-55 are rejected under 35 U.S.C. 103(a) as being unpatentable over Fuenzalida et al. (EP 952,208), Jones et al. (Metabolism, 1998), Cleary (US 4,495,094), Sorkin, Jr. (US 5,952,393) and Milstein et al. (US 6,394,230) in combination.

Fuenzalida et al. teaches the presence of fatty alcohols, sterols, stanols and sterol esters in tall oil (see the entire article, especially sections 0003-0007, 0050, 0057, 0068, 0071, 0076). The reference teaches (a) fatty alcohols such as docosanol, eicosanol, hexacosanol and tetracosanol and sterols such as β-sitosterol, β-sitostanol, campesterol, campestanol and stigmasta-3-one (see especially Tables 1-6) and (b) stanol and stanol esters in formulation of diets are known to reduce plasma level of cholesterol (see section 0007).

Claims 36, 38, 39, 40-42 and 44-55 differ from the reference by reciting "octadecanol".

However, Cleary teaches the presence of octadecanol in tall oil (see the entire article, especially Example II). Therefore, the skilled artisan in the art would have the reasonable expectation that the composition taught by Fuenzalida would contain some amounts of octadecanol.

Claims 38-45 differ from the reference by reciting food substances containing a mixture the claimed fatty alcohol and/or sterols in various amounts.

However, the incorporation of cholesterol-lowering agents into food substances such as margarine is known in the art (see **Jones**, page 751, 1st paragraph and **Milstein** et al., col. 1, lines 18-35). The determination of the amounts that would effectively lower cholesterol levels would require only routine experimentation which is done regularly in the pharmaceutical art and, thus, was within the level of skill of the ordinary artisan in the art at the time of the present invention. Therefore, the recitation of amounts in the instant claims is not patentable absence a showing of criticality.

Claims 39, 41, 45, 47, 49, 51, 53 and 55 differ from the reference by reciting the combination of fatty alcohols and phytosterols and Claims 52 and 53 differ from the reference by reciting a method of reducing serum cholesterol levels.

However, Sorkin teaches a composition comprising phytosterols and policosanols for reducing serum cholesterol levels (see the entire articles, especially col. 1, lines 5-8; col. 3, lines 11-26; examples 1 and 2). The reference teaches (a) phytosterols such as β-sitosterol, campesterol and stigmasterol and (b) policosanols

ranging from 20-39 carbon atoms in length, such as docosanol, tetracosanol, hexacosanol and octacosanol (see col. 2, lines 27-31 and Table I; col. 3, Table II). As stated by Sorkin, the utilization of phytosterols and policosanols (i.e., fatty alcohols) in lowering plasma cholesterol levels is well known in the art (see also, **Fuenzalida et al.**, section 0007; **Jones et al.**, pages 755-756, Discussion; and **Milstein et al.**, col. 1, lines 39-45). Therefore, the combination of the phytosterols and policosanols of Fuenzalida et al. as taught by the Sorkin would be prima facie obvious. The motivation is based on the teachings of prior art said combination would lower cholesterol levels.

In summary, based on the combined teachings of the cited prior art, (a) the presence of fatty alcohols and sterols as recited by instant claims in tall oil, (b) the utilization of said substances, irrespective of the origin, in food substances for the lowering of cholesterol levels in the plasma is prima facie obvious.

Response to Arguments

7. Applicant's argument against the 103 rejection made in the previous Office Action is noted. Briefly, applicant argues (a) none of the cited references cited taught a mixture/formulation derived from tall oil, (b) *In re Russell* does not hold when the proportions are not taught by the art, (c) the examiner did not address the limitations such as dosage amounts and wt. percentages of the dependent claims, (d) policosanols from different natural sources are not readily interchangeable and (e) there is no reasonable expectation of success in achieving hypocholesterolemic activity with

policosanols and phytosterol mixtures derived from tall oil. Applicant's argument was not persuasive for the following reasons.

First, it would be obvious to a skilled artisan in the art that irrespective of the source of a chemical compound, its property would be identical. That is, the activity of a compound is not dependent on the source of that compound. Therefore, the skilled artisan would not expect identical mixtures of policosanols and/or phytosterols obtained from different sources wherein the amount of each individual compound in each mixture is identical to show different biological properties. The examiner notes applicant's reference to US Patent No. 6,465,526 for support of said argument. However, the reference does not show the make-up of each mixture and, thus, one cannot assume the difference in activity is due to the source from which it was obtained.

Applicant also argues that pure hexacosanol and pure octacosanol showed no statistically significant cholesterol-lowering effect (US Patent No. 5,663,156). It is noted that the reference (a) states the effect was not statistically significant and not that the compounds do not possess said activity, (b) shows the effect of a single dose, i.e., 5mg/kg and (c) does not show the effect of the combination of the two at the same dose. The skilled artisan evaluating the reference would have the reasonable expectation that increase amounts of the compounds will have greater cholesterol-lowering effect and he would also have the reasonable expectation that combination of the two compounds in the amount taught by the reference will have an additive effect and, thus, a greater cholesterol-lowering effect. There is no evidence of record showing that said expectation would be wrong.

Lastly, even if one agrees that absence a teaching of ranges that overlap that of the claimed invention that *In re Russell* does not apply, the fact remains that the determination of dosages that would result in optimum activity is routine in the pharmaceutical art. Therefore, when the difference between the claimed invention and the prior art is one of concentration/amounts of the active ingredients, the burden is on applicant to show that said proportions are critical to the claimed invention. The present specification lacks a showing of the criticality of the recited ranges.

Telephone Inquiry

8. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Barbara P. Badio, Ph.D. whose telephone number is 571-272-0609. The examiner can normally be reached on M-F from 6:30am-4:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sreenivasan Padmanabhan can be reached on 571-272-0629. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should

you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Barbara P. Badio, Ph.D.
Primary Examiner
Art Unit 1617

BB
May 22, 2006